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SN 09/415,890

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March 24, 2004 Date

David L. Parker

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Re-

SN 09/415,890 entitled "Pharmacologically Acceptable Solvent Vehicles" by

Andersson

Our ref: UTXC:528-1 Clie

Client ref: MDA96-033 CON1

Commissioner:

Enclosed please find an Amendment and Response to Official Action Dated January 26, 2004 for filing in the above-referenced patent application.

Should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/UTXC:528--X

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DLP/lb Enclosure

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PATENT

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date below:

March 24, 2004

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Borje S. Andersson

Serial No.: 09/415,890

Filed: October 8, 1999

For: PHARMACOLOGICALLY

ACCEPTABLE SOLVENT VEHICLES

Group Art Unit: 1616

Examiner: Neil Levy

Atty. Dkt. No.:UTXC:528--1/DLP

I. AMENDMENT; AND II. RESPONSE TO OFFICIAL ACTION DATED JANUARY 26, 2004

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

This paper is submitted in response to the Official Action dated January 26, 2004, for which the three-month date for response is April 26, 2004. It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski Deposit Account No. 50-1212/UTXC:528--1.

I. AMENDMENT

Please amend the application as follows:

- 1.-93. (Cancelled)
- 94. (Withdrawn) The method of claim 93, where the acid is acetic acid.
- 95. (Withdrawn) The method of claim 93, where the dipolar aprotic solvent and/or acid is virtually eliminated from the solvent vehicle.
- 96. (Withdrawn) The method of claim 93, where removing the dipolar aprotic solvent and/or acid is by lyophilization.
- 97. (Currently Amended) A method for preparing a pharmaceutically acceptable solvent vehicle, the method comprising:
 - (a) obtaining a pharmaceuctically acceptable dipolar aprotic solvent and/or acid;
 - (b) mixing the dipolar aprotic solvent and/or acid in a pharmaceutically acceptable aqueous secondary solvent that optionally comprises one or more lipids;
 - (c) removing more than 50% of the dipolar aprotic solvent and/or acid and aqueous secondary solvent; and
 - (d) reconstituting the solvent vehicle by the addition of a pharmaceutically acceptable aqueous solvent.
- 98. (Previously Presented) The method of claim 97, wherein said pharmaceutically acceptable aqueous solution comprises water, saline solution, dextrose solution, aqueous lipid emulsion, glacial acetic acid, or lipid solution.
- 99. (Previously Presented) The method of claim 97, further comprising the step of dissolving pimaricin in said dipolar aprotic solvent and/or acid prior to mixing in a pharmaceutically acceptable aqueous secondary solvent.

- 100.-105. (Cancelled)
- 106. (Withdrawn) The method of claim 93, wherein the dipolar aprotic solvent or acid is eliminated.
- 107. (Withdrawn) The method of claim 93, wherein the removing dipolar aprotic solvent or acid removes 95% of the dipolar aprotic solvent or acid.
- 108. (Withdrawn) The method of claim 107, wherein the removing dipolar aprotic solvent or acid removes 99% of the dipolar aprotic solvent or acid.
- 109. (Withdrawn) The method of claim 93, wherein said aprotic solvent comprises N,N-dimethylacetamide, castor oil, dimethylsulfoxide, 1,2,-propylene-diol, glycerol or polyethylene glycol-400.
- 110. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises N,N-dimethylacetamide.
- 111. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises castor oil.
- 112. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises dimethylsulfoxide.
- 113. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises 1,2,-propylene-diol.
- 114. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises glycerol.
- 115. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises polyethylene glycol-400.

- 116. (Previously Presented) The method of claim 97, wherein said secondary solvent comprises aqueous lipid emulsion, water, saline solution, dextrose solution, glacial acetic acid, or lipid solution.
- 117. (Previously Presented) The method of claim 116, wherein said secondary solvent comprises an aqueous lipid emulsion.
- 118. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises emulsified fat particles of about 0.4 micron in diameter.
- 119. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises an aqueous soy bean lipid emulsion.
- 120. (Previously Presented) The method of claim 119, wherein said aqueous soy bean lipid emulsion comprises soy bean oil, lecithin, glycerin and water.
- 121. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises a lipid component that includes at least one vegetable oil and at least one fatty acid.
- 122. (Previously Presented) The method of claim 121, wherein said lipid component comprises at least about 5% by weight soybean oil and at least about 50% by weight fatty acids.
- 123. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises water.
- 124. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises saline solution.
- 125. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises dextrose solution.
- 126. (Withdrawn) The method of claim 125, wherein said dextrose solution comprises 5% to 70% dextrose in water.

- 127. (Withdrawn) The method of claim 126, wherein said dextrose solution comprises 5% or 10% dextrose solution.
- 128. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises glacial acetic acid.
- 129. (Withdrawn) The method of claim 93, wherein said secondary solvent comprises a lipid solution.
- 130. (Withdrawn) The method of claim 93, wherein said secondary solvent comprises a parenteral infusion fluid.
- 131. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and polyethylene glycol-400.
- 132. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises glacial acetic acid and polyethylene glycol-400.
- 133. (Previously Presented) The method of claim 97, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and aqueous lipid.
- 134. (Previously Presented) The method of claim 133, wherein said aqueous lipid is an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.
- 135. (Previously Presented) The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 1:10 volume ratio.
- 136. (Previously Presented) The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide diluted with 9 volumes 20% of an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

- 137. (Previously Presented) The method of claim 134, wherein said solvent vehicle further comprises normal saline or 5% dextrose solution.
- 138. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400 and 1,2-propylene diol.
- 139. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide.
- 140. (Withdrawn) The solvent vehicle of claim 139, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide in equal volume ratios.
- 141. (Previously Presented) The method of claim 97, wherein said vehicle comprises glacial acetic acid, and wherein said vehicle further comprises anhydrous N,N,-dimethylacetamide, dimethylsulfoxide or an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.
- 142. (Previously Presented) The method of claim 150, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.
- 143. (Previously Presented) The method of claim 142, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide, and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 2:6:3 volume ratio.
- 144. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises water.
- 145. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises saline solution.

- 146. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises dextrose solution.
- 147. (Withdrawn) The method of claim 146, wherein said dextrose solution comprises 5% to 70% dextrose in water.
- 148. (Withdrawn) The method of claim 147, wherein said dextrose solution comprises 5% or 10% dextrose solution.
- 149. (Withdrawn) The method of claim 98, wherein said secondary solvent comprises a parenteral infusion fluid.
- 150. (Previously Presented) The method of claim The method of claim 97, wherein said solvent vehicle comprises glacial acetic acid and an aqueous lipid emulsion.